K093889

HIOSSEN

Hiossen Inc.
85 Ben Fairless Dr. Fairless Hills, PA 19030
Tel : 1-888-678-0001 / Fax : 1-267-759-7004
www.hiossen.com

APR 22 2010

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date : December 4, 2009

1. Company and Correspondent making the submission:

- Submitter's Name :	HiOSSEN Inc.
- Address :	85 Ben Fairless Dr. Fairless Hills PA 19030
- Telephone No.	888 678 0001
- Contact :	Mr. Patrick Lim

2. Device :

Trade or (Proprietary) Name :	HGⅢ Ultra wide Fixture System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE

3. Predicate Device :
The HGⅡ Ultra wide Fixture System, HiOSSEN Inc, K073465

4. Description :
1) The HGⅢ Ultra wide Fixture System is dental implant made of titanium metal intended to be used in the molar region and surgically placed in the bone of the upper or lower jaw arches. Fixture is made of pure titanium metal and supplied sterile. The surface is RBM, Resorbable Blast Media, treated.

HGⅢ Ultra wide Fixture is composed of single threads with internal hex connection taper body of bone level for two stage surgery. It has RBM surface.

2) The HGⅢ Ultra wide Fixture System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

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3) The HGⅢ Ultra wide Fixture System is substantially equivalent in design, function and intended use to the HGⅡ Ultra wide Fixture System (K073465) of HiOSSEN Inc.

- Substantial Equivalence Matrix

	HGⅢ Ultra wide Fixture	Predicate devices HGⅡ Ultra wide Fixture (K073465)
Manufacturer	HiOSSEN Inc.	HiOSSEN Inc.
Intended Use	The HGⅢ Ultra wide Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The HGⅢ Ultra wide Fixture System is for single and two stage surgical procedures. It is not for immediate load. The HGⅢ Ultra wide Fixture System is intended to be used in the molar region.	The HGⅡ Ultra wide Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The HGⅡ Ultra wide Fixture System is for single and two stage surgical procedures. It is not for immediate load. The HGⅡ Ultra wide Fixture System is intended to be used in the molar region.
Structure	-Single Thread -Taper body Type -Self tapping	-Single Thread -Straight body Type -Self tapping
Connection Type	Internal hex connection	Internal hex connection
Diameter (D)	6.0~7.0	6.0~7.0
Length (mm)	7.0~13.0	7.0~13.0
Material of Fixture	Pure Titanium Grade 4 (ASTMF67-06)	Pure Titanium Grade 4 (ASTMF67-06)
Surface	RBM	RBM
Packaging	Polymeric Ampoule in a foil backed peel open blister pack	Polymeric Ampoule in a foil backed peel open blister pack
Sterilization	Radiation Sterile	Radiation Sterile
Shelf life	5 years	5 years
S & E	No changes in function and intended use	

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5. Indication for use :
The HGIII Ultra wide Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The HGIII Ultra wide Fixture System is for single and two stage surgical procedures. It is not for immediate load. The HGIII Ultra wide Fixture System is intended to be used in the molar region.

6. Review :
The HGIII Ultra wide Fixture System has same material and indication for use and similar design and technological characteristics as the predicate device.

The HGIII Ultra wide Fixture System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Summary of nonclinical testing
Fatigue testing was conducted according to the "Guidance for industry and FDA staff Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario of the GSIII Fixture(or HGIII Fixture) and an angled abutment in support of the HGIII Ultra Wide Fixture.
Therefore, the fatigue test result of GSIII Fixture System (or HGIII Fixture System) can be used as a proof of HGIII Ultra Wide Fixture since HGIII Ultra Wide Fixture has large diameter.

8. Conclusion :
Based on the information provided in this premarket notification HiOSSEN concludes that the HGIII Ultra wide Fixture System is safe and effective and substantially equivalent to the predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. Patrick Lim
Manager
Hiossen, Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

APR 22 2010

Re: K093889
Trade/Device Name: HGIII Ultra Wide Fixture System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: April 1, 2010
Received: April 9, 2010

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K 093889

Device Name : HGIII Ultra wide Fixture System

Indication for use : The HGIII Ultra wide Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including ; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. The HGIII Ultra wide Fixture System is for single and two stage surgical procedures. It is not for immediate load. The HGIII Ultra wide Fixture System is intended to be used in the molar region.

Prescription Use X (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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